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Group Art Unit No.: 3731

Reply to the Office Communication dated May 16, 2006

### **REMARKS/ARGUMENTS**

Claims 1 through 11, and 20 through 26 are pending in the instant application. Claims 1, 19, 20, 21, and 26 are the five (5) independent claims. Claims 2 through 11 depend from claim 1. Claims 12 through 18 have been cancelled without prejudice. Claims 20 through 26 are newly added. New claims 22 through 25 depend from claim 21.

#### **I. Restriction/Election**

During a provisional telephonic election with the Examiner, Applicants duly elected the invention of invention I or claims 1 through 11, and 19. Applicants herein confirm the provisional election that was made on May 4, 2006, of invention I, or claims 1 through 11, and 19 as requested by the Office. Applicants herein also cancel the claims directed to invention II, or claims 12 through 18 without prejudice and reserve the right to file a divisional patent application directed to those claims in the future. Applicants note that new claims 22 through 26 read on the elected invention, or invention I. Applicants respectfully request that these claims be entered into the application.

#### **II. Claim Rejections under 35 U.S.C. § 102(b)**

##### **a. United States Patent No.: 5,921,996 to Sherman**

In the Office Action, claim 19 is rejected under 35 U.S.C. § 102(b) in view of United States Patent No. 5,921,996 to Sherman (hereinafter "Sherman"). Applicants respectfully submit that Sherman does not disclose or suggest all of the elements in the independent claims.

Claim 19 recites a kit comprising a clip applying apparatus including a handle

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assembly and a body portion defining a longitudinal axis. The apparatus also has a plurality of jaw mechanisms. The jaw mechanisms have first and second jaws with a predefined radius of curvature.

The radius of curvature of the first and second jaws is different from the radius of curvature of each of the first and second jaws of each of the other of the plurality of jaw mechanisms.

The Office incorrectly indicates that Sherman discloses a clip applier on page 4 of the Action. The instrument of Sherman has a dial that is used to lock the clamp on the clamp applier and to remove the clamp from the clamp applier. As shown on column 4, lines 26, the clamps are made from two pieces of plastic and have tissue clamping surfaces. The surfaces are made from a soft compressible material to minimize tissue on the areas contacted. In no way does Sherman disclose the present kit.

Sherman does not disclose or suggest any kit with a clip applying apparatus. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. See Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The clamp applier of Sherman does not release occlusion clips for ligation purposes and Applicants contend that this is improperly cited art. The clamps of Sherman are between 2.0 and 10.0 centimeters.

These clamps are suitable for clamping the aorta and the pulmonary vein, and do not release clips from the instrument. See column 4, lines 1 through 10. Instead, the clamp is applied, and once the surgery is complete, the surgeon will remove the entire clamp from the vessel or vein.

In contrast, the present kit comprises a clip applying apparatus that can be a manual or a multiple clip applicator which may include a stack or series of clips positioned within central body portion of clip applying apparatus. Such a device may include clip feeding and may also include advancing mechanisms as described in the specification. Reconsideration and withdrawal of the rejection of claim 19 are requested.

**III. Claim Rejections under 35 U.S.C. § 103(a)**

**a. United States Patent No. 5,797,959 to Castro, et al.**

In the Office Action, claims 1, 2, and 7 are rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over United States Patent No. 5,797,959 to Castro, et al., (hereinafter "Castro"). It is respectfully submitted that the limitations of each of these claims is not taught or suggested by Castro.

Claim 1 recites a clip applying apparatus. The apparatus has a handle assembly and a body portion defining a longitudinal axis and extending distally from the handle assembly. Claim 1 also provides for a jaw mechanism that includes first and second jaws configured to receive a clip therebetween. The first jaw moves in relation to the second jaw between open and closed positions. Each jaw is curved upwardly towards a distal end along the longitudinal axis of the body portion. Each upwardly curved jaw has a radius of curvature "r" of between about .5 inches and about .9 inches.

Castro discloses a surgical clamp. The apparatus has a clamp on a distal end that is normally prepared for insertion into the body cavity by placing jaw assemblies and in a closed position corresponding to pivoting handle so the handle is in approximation with stationary handle.

The apparatus can then be inserted in the body cavity either through a cannula or a small incision. Once inside the body cavity, jaw assemblies and may be remotely manipulated at handle assembly. In particular, trigger is depressed to disengage pawl from engagement with rack. By maintaining pressure on trigger, pivoting handle may be opened, thereby camming jaw assemblies and to an opened position. Turning rotation knob in incremental movements is performed to rotate jaw assemblies to the desired angular orientation near a blood vessel or tissue structure.

After the positioning of the jaw assemblies about the tissue to be grasped, closure of the jaws is achieved by approximating the pivoting handle with the stationary handle. The user will detect either audibly or in a tactile sense the progressive engagement of pawl with rack. Removal of surgical apparatus from the operative site is normally achieved by closing jaw assemblies and returning them to the non-articulated or straightened configuration. In other words, the jaw assemblies clamp tissue between the jaw portions and act as a Fogarty clamp, an aortic clamp where the jaws are selectively placed over the desired tissue and left clamped on the tissue.

The Examiner agrees that the cited reference does not disclose or suggest any jaw configuration with the claimed radius of curvature configuration as claimed in Claim 1. The Examiner admits this at page 5 of the Action. However, Castro also does not disclose or suggest any clip applier or any jaws that are configured to receive a clip between the jaws.

The instrument of Castro does not disclose or suggest any such jaw configuration and in fact teaches away from such a configuration by disclosing that the jaws of the Castro instrument may have a Fogarty clamp configuration where the distal jaw portion includes a body portion that cannot be used or configured as a clip applier. Castro's instrument has a generally elongated configuration and jaws with two rows of interdigitating teeth 270 and 272 that are formed along the length of distal jaw portion, with one row being disposed adjacent each peripheral edge of the jaw.

A channel 274 extends between rows 270 and 272 along a medial portion of the jaw to receive tissue gripped by the rows of teeth. The curvature of the jaw enables the surgeon to reach and clamp blood vessels using the jaws not any clips and other structures without interfering with neighboring tissue. Applicant contends that this teaching away rebuts the Office's assertion of obviousness. It is improper to combine references where the references teach away from their combination. See *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

After reviewing that the jaws are to have teeth to assist with the clamping, one of ordinary skill in the art would not be motivated to alter the jaws to provide that the jaws are configured to receive a clip therebetween. In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification. See *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

After reviewing the teaching of Castro one would not be motivated to alter Castro as claimed, and in fact could not make the modification since the teeth and channel would interfere with ejecting a clip for occlusion purposes. Reconsideration and withdrawal of the rejection of claim 1 are respectfully requested. Claims 2 and 7 are believed to be patentable for at least the reasons discussed above for claim 1.

**b. United States Patent No. 5,626,586 to Pistl, et al., in view of United States Patent No. 4,325,376 to Klieman, et al.**

In the Office Action, claims 1 through 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable as obvious over United States Patent No. 5,626,586 to Pistl, *et al.*, (hereinafter "Pistl") in view of United States Patent No. 4,325,376 to Klieman, *et al.*,

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("Klieman"). It is respectfully submitted that the limitations of each of these claims is not taught or suggested by the references alone or in combination with one another.

Pistl discloses an apparatus for applying surgical clips. The apparatus has a pistol grip actuator having an operating grip. The grip moves from an intermediate position in a first direction for setting one of the surgical clips and in a second direction for disassembly of the apparatus. The apparatus has a removable magazine with an elastic catch biased downward for engaging a catch member of a hollow shaft extending through a forceps closing member.

Klieman discloses a hemostatic clip applier. The clip applier has a pair of jaws and a clip magazine coupled to the exterior of a main body. The clip magazine has a housing. The housing holds clips. The clip applier also has a clip feeder that is slideably disposed within the magazine and moving clips from the clip magazine to the jaws.

The clip applier has a clip loader connected to the clip feeder for moving clips through the housing. The clip loader has a ratchet bar coupled to the clip feeder and a pawl selectively coupled to the ratchet bar for urging clips through the housing.

The Office cites on page 6 of the Action that Pistl discloses "*what appears to be curved jaw members in Fig. 2, but Pistl[,] et al. does not expressly — [sic] — disclosed curved jaws in the text*".

Applicant has reviewed Figure 2, and respectfully disagrees with the Office. Applicant notes that the claim limitation of claim 1 recites "*a jaw mechanism including first and second jaws configured to receive a clip therebetween, the first jaw being movable in relation to the second jaw between open and closed positions, each jaw being curved upwardly towards its distal end along the longitudinal axis of the body portion, each curved jaw having a radius of curvature "r" of between about .5 inch and*

*about .9 inch".*

The jaws are not curved, let alone curved upwardly. Instead, the jaws are straight planar members as shown in Fig. 2 that merely tilt downwardly. The jaws do not curve along the longitudinal axis as claimed.

The Office also states that on page 6 through 7 of the Action that "*Kleinman, et al. discloses that it is old and well known to provide a jaw mechanism that has upwardly curved jaw members. Klieman, et al. further discloses that the curved jaw members provide increased visibility during usage (col. 6, lines 59 through 63). Klieman, et al. does not disclose a radius of curvature between about 0.5 inches and 0.9 inches*".

Applicants have reviewed the relevant passages at column 6, lines 59 through 63. The Office is misquoting the passage by stating that the jaws curve "*upwardly*" or by stating that this novel feature is "old" or "well known" which are respectfully not in the passage. The passage states that:

FIG. 4 is a top view of clip applying device 2. Illustrated here is the relationship between main body 20, lower finger loop member 7 and upper jaw portion 32. It can be seen that lower finger loop member 7 is fixedly coupled to upper jaw portion 32 and lower finger loop 6, while the combination of member 7 and jaw portion 32 is pivotally coupled to main body 20 by upper jaw pivot 36. Thus, rotation of member 7 about pivot 36 by movement of lower finger loop 6 results in rotation of upper jaw 32 about pivot 36. Therefore, inward and outward movement of lower finger loop 6 will result in movement of upper jaw portion 32 toward and away from lower jaw portion 34. **Also shown in FIG. 4 is the curved configuration of upper jaw portion 32 and lower jaw portion 34. This curved forward portion of clip applying device 2 provides the distinct advantage of improved — [sic] — visibility during usage since the vessel which is to be closed will be located to one side or the other of the main body 20. Although the presently preferred embodiment of the upper and lower jaw portions utilizes a curved configuration, other configurations, such as straight jaw portions, may be used.** Further illustrated in FIG. 4 are top views of clip magazine 102, guide spring means 100, second spring means 22 with its rivets 23, along with ratchet spring 106 and ratchet teeth 108. (Emphasis added).

Applicants have reviewed Figure 4 and the reference does not disclose or suggest any jaw being curved upwardly towards its distal end along the longitudinal axis of the body portion with each curved jaw having a radius of curvature "r" of between about .5 inch and about .9 inch. The jaws are not curved upwardly, and instead are straight planar members as shown in Fig. 4 that move downwardly to assist with visibility.

Applicants contend that Pistl, Klieman, and the combination thereof do not disclose or suggest any clip applying apparatus that has a jaw mechanism with first and second jaws configured to receive a clip therebetween having each jaw curved upwardly towards its distal end along the longitudinal axis of the body portion.

Pistl, Klieman, and the combination thereof also do not disclose or suggest that each upwardly curved jaw has a radius of curvature "r" of between about .5 inches and about .9 inches.

Applicants contend that the references alone or in combination with one another further do not recognize the problems that the upwardly curved jaw configuration having the claimed radius of curvature remedies. The benefits of the presently disclosed curved jaws of the clip applying apparatus include the improved ability to separate tissue from surrounding tissue and manipulate tissue at the surgical site. In this configuration, the tips are useful. This is not shown in the art since typically distal tips of clip applier do not manipulate tissue at the surgical site as this may cause a clip to fall out or be dislodged from between the jaws. This causes additional time to be wasted and reloading. Neither of the cited references recognizes this unexpected and novel benefit.

It is therefore respectfully submitted that Pistl, Klieman, and the combination thereof does not in any fashion anticipate, teach or suggest all of the limitations of claim 1. Reconsideration and withdrawal of the rejection of claim 1 are therefore requested.



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Claims 2 through 11 are patentable for reasons similar to those argued above for claim 1. Reconsideration and withdrawal of the rejection of those claims are also respectfully requested.

#### **IV. Newly Added Claims**

New claim 20 is also patentable over the cited and relied upon references. None of the references disclose or suggest any kit with a clip applying apparatus including a handle assembly, a body portion defining a longitudinal axis and a plurality of jaw mechanisms with the body portion defining a clip carrying channel having clips and a feed bar configured to feed a clip to at least one jaw mechanism and wherein each of the plurality of jaw mechanisms including first and second jaws having a predefined radius of curvature wherein the radius of curvature of the first and second jaws of each of the plurality of jaw mechanisms is different from the radius of curvature of each of the first and second jaws of each of the other of the plurality of jaw mechanisms. Moreover, none of the references disclose or suggest that each of the jaw mechanisms has a radius of curvature that curves upwardly.

Newly added claim 21 is also patentable over the cited and relied upon references. None of the references alone or in combination disclose or suggest a jaw mechanism including first and second jaws configured to receive a clip therebetween with each jaw having a distal end, a proximal end extending out of the body portion, and a lateral edge wherein from the proximal end to the distal end the lateral edge moves in a direction spatially oriented from a lower elevation at the proximal end to a higher elevation at the distal end with a radius of curvature "r" of between about .5 inch and about .9 inch. Claims 22 through 25 depend from claim 22 and are patentable for at least the reasons discussed above for claim 21. New claim 26 is also patentable for reasons similar to those argued above for claim 21.

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**V. CONCLUSION**

It is believed that all the claims of the application as now presented, *i.e.*, claims 1 through 11, and 19 through 26, are in condition for allowance. In view of the foregoing amendment and remarks, early and favorable reconsideration of this application is respectfully requested.

Respectfully submitted,  


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